

## GENERAL INSTRUCTIONS FOR PREPARATION OF P01 CRITIQUES

Please bring three, double-spaced typed copies of the reviews assigned to you to the meeting. In addition, bring your critiques on a disc, and indicate which word processing program has been used and whether it is PC- or MacIntosh-based. This will facilitate the writing of the summary statements. You will be given a disc in exchange at the meeting.

For PRIMARY REVIEWERS of INDIVIDUAL PROJECTS:

1. Overall Evaluation Briefly summarize the most important points of your critique, weighting the review criteria as you feel appropriate. Evaluate the overall impact on the field.
2. Description This section is optional: you may summarize succinctly the proposed research from the information provided by the investigator or utilize the abstract from the application. Do not evaluate the application in this section.
3. Critique Using the guidelines for review, evaluate the significance, approach, innovation, investigator, and environment of the proposed research. Address each criterion as a separate heading. If this is a competing renewal application, evaluate the progress made during the previous funding period either as a separate paragraph or under the individual criteria as appropriate.
4. Budget If any changes are recommended, provide a justification along with a specific dollar amount.
5. Recommendation Unless recommended for no further consideration, assign a merit descriptor term/priority score.

For PRIMARY REVIEWERS of CORES:

1. Overall Evaluation Briefly summarize the most important points of your critique.
2. Description This section is optional: you may summarize succinctly the proposed research from the information provided by the investigator or utilize the abstract from the application. Do not evaluate the application in this section.
3. Critique Using the guidelines for review, evaluate the core's utility to the program, quality of facilitates or services provided, qualifications of personnel. If this is a competing renewal application, evaluate the progress made during the previous funding period.
4. Budget If any changes are recommended, provide a justification along with a specific dollar amount.
5. Recommendation Unless recommended for no further consideration, assign a merit descriptor term.

SECONDARY REVIEWERS need only prepare written critiques addressing the five criteria and recommendations, although comments on any other sections will be welcome.

READERS should have read the assignment carefully and be conversant with it but are not required to supply a written critique, although it will be appreciated.

For the OVERALL PROGRAM PROJECT CRITIQUE:

Focus on the scientific merit and impact of the program project on the field and on the strengths and weakness of the application, using the concepts of in light of the significance, approach, innovation, investigators, and environment that the entire research effort provides. In addition, the factors of cohesiveness, synergy, and progress (for competing renewals) must be taken into account. In arriving at an overall assessment, a brief summary of the merit of individual projects and cores should outline the compelling reasons which resulted in the evaluation each received.

SUPPORT TO BE NEGOTIATED is a section included in P01 and multiproject applications, although such items should be noted in any application which you review. Any real or potential duplication of scientific aims or excessive effort (greater than 100%) by an investigator should be listed (Smyth, John (PI); R01 DK12345-04; overlapping aims). These issues will be resolved administratively, in the event of awarded funding.

SCIENTIFIC/BUDGETARY OVERLAP, if identified in an application, should be noted in a statement separate from the critique and should not be considered in the evaluation of the application. The Scientific Review Administrator will ensure that such issues are documented in the summary statement as an administrative note. Purported overlap must be resolved by NIH staff before an award is made.

FOR COMPETING RENEWAL APPLICATIONS (Type 2), evaluation of the progress and achievements specific to the application under review must be assessed. The application must state clearly when publications have resulted from support through more than one funding source. Equivocal information may affect the review of the application.

### **HUMAN SUBJECTS AND ANIMAL WELFARE CONCERNS**

Human subjects concerns are important to the NIH. As you evaluate the treatment of human subjects as proposed in the application, please weigh the risks and benefits to the subjects of entering a protocol and indicate whether: (a) they will be at risk as the result of a procedure; (b) an informed consent form has been reviewed by an Institutional Review Board; (c) procedures have been included to deal with potential untoward effects of a treatment; and (d) measures have been taken to protect the anonymity of the subjects. For those applications that deal with human subjects, an indication of concern or no concern should be given as regards treatment of patients.

In conformance with NIH policy, the use of women, children, and minority individuals in patient populations is an issue that should be addressed in any application which involves clinical research. Clinical research includes "...human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials" (OER 90-5). If there is no compelling rationale provided for the exclusion or under-representation of women, children, and minorities from the patient study population, this constitutes a flaw in experimental design and should be reflected in the priority score. Reviewers are asked to inform the Scientific Review Administrator before the review if such concerns exist and to comment specifically on these issues in their critiques. In addition, you will be asked to recommend a code for the application.

Careful scrutiny also should be given to treatment of animals in experimental protocols. The following issues shall be addressed in the application: (a) the identification of the species and approximate number of animals required; (b) the rationale for using animals and the appropriateness of the species and numbers indicated for the work proposed; (c) a complete description of the anticipated use of the animals; (d) an assurance that discomfort and injury to animals will be limited to unavoidable situations and that analgesic, anesthetic, and tranquilizing drugs will be employed where possible to minimize discomfort and pain; and (e) a description of any euthanasia method to be applied. Please indicate in your written critique if you have reason to be concerned over any of these issues.

If biohazardous materials are to be used in the proposed research, the principal investigator should address the proper handling of such items.